

EXHIBIT C



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
 United States Patent and Trademark Office
 Address: COMMISSIONER OF PATENTS AND TRADEMARKS
 Washington, D.C. 20231
 www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/137,169	05/02/2002	Keith G. Copeland	97,008-Y	2031

20306 7590 02/05/2003

MCDONNELL BOEHNEN HULBERT & BERGHOFF
 300 SOUTH WACKER DRIVE
 SUITE 3200
 CHICAGO, IL 60606

EXAMINER

BEX, PATRICIA K

ART UNIT

PAPER NUMBER

1743

DATE MAILED: 02/05/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

10/137,169

COPELAND ET AL.

Examiner

Art Unit

P. Kathryn Bex

1743

- The MAILING DATE of this communication appears on the cover sheet with the correspondence address -

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 October 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 72-115 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 72-115 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4, 6.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

Application/Control Number: 10/137,169

Page 2

Art Unit: 1743

DETAILED ACTION

Specification

1. Applicant is reminded of the proper language and format for an abstract of the disclosure. Legal phraseology often used in patent claims, such as "means" and "said," should be avoided.
2. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 72-155 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. The omitted elements are: air mixer having a nozzle for directing air at an air agitation zone of the sample support for mixing reactants on the sample support. It is not clear from the claim as presently written where the air agitation zone is, or if the air mixer interacts the sample support.

Claim 97, line 2, "the air distribution manifold" lacks antecedent basis. Same deficiency was found in claim 99.

Claim 102, line 3, "the application station" lacks antecedent basis.

Claim 112, "the rinse zone" lacks antecedent basis.

Application/Control Number: 10/137,169

Page 3

Art Unit: 1743

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. Claims 72-82, 91-96, 101-106 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hulette (WO 85/03571) in view of Kelln et al (USP 4,764,342).

Hulette teaches an analyzer system for the analysis of biological samples, wherein the sample is placed on a rotating carousel, or belt 22, and positioned below a reagent tablet dispenser 40 with carousel 42. The dispensers are detachable and can be loaded randomly (page 15, lines 16-27). The system includes a bar code reader 66 which reads information from the bar code on the sample cuvette, this information is transferred to the control microprocessor. The location of the cuvette on the belt is correlated with the information on the cuvette. Moreover, Hulette teaches the use of an air-jet mixing apparatus 15a to provide thorough mixing of the cuvette contents and the reagent. The air-jet directs an air jet at an acute angle against the liquid surface adjacent its junction with the cuvette wall to create a vortex. Hulette does not disclose

the use of the reagent carousel with a homing and indexing means. However, the use of a reagent carousel with a homing and indexing means is considered conventional in the dispensing art, see Kelln et al.

Kelln et al teach an analyzer system with a rotating reagent carousel 132 for housing a plurality of reagent containers and a rotor for positioning the reagent containers at a loading station 108. The table 132 loaded with reagent containers 10 is then inserted onto upstanding shaft 176 in driving engagement therewith as indicated in FIG. 11. After table 180 is so positioned, sample support table 166 is indexed to position aperture 172 in alignment with optical reader 174, and then table 132 is indexed by a stepper motor via shaft 176 (forty steps per reagent position) to read the barcode information 54 on the reagent containers 10 and store that reagent identification information in the memory of the analyzer control system. The position of each of the twenty reagent containers 10 is established with reference to slot 178 of drive shaft 176. Similarly, the angular position of each of the sample containers 128 is established relative to drive hub 170 by the interengaged notch 162 and key 164.

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided the apparatus of Hulette with a reagent carousel with a homing and indexing means, as taught by Kelln et al, in order to provide a system which permits versatile use of reagents in an automated analysis system so that a number of different tests (profile) can be run utilizing a single analysis rotor and several different reagents on a common sample, as well as other types of analysis procedures in which the same analysis is run on several different samples using a single analyzer rotor. The operation being under system

Application/Control Number: 10/137,169

Page 5

Art Unit: 1743

control thereby avoiding potential errors and the manual handling aspects of reagent and analysis rotor (column 3, lines 19-34).

With respect to the use of a slide it would have been obvious to one of ordinary skill in the art to have replaced the cuvette of Hulette with a slide carousel, since microscope slides and cuvettes are known equivalents for biological analysis the analyzer art, see (Kamentsky et al, USP 5,107,422, col.4, lines 22-25).

With respect to the use of a metal proximity detector in the reagent and slide carousel, it would have been obvious matter of design choice to replace the optical sensor of Hulette with a metal proximity sensor, since applicant has not disclosed that a metal proximity sensor solves any stated problem or is for any particular purpose and it appears that the invention would perform equally well with an optical sensor.

8. Claims 72-79, 102-106 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sakurada (USP 4,346,056) in view of Rokugawa (USP 4,844,868) and Gibbs *et al* (USP 3,854,703).

Sakurada teach an automated biological reaction apparatus having a releasable reagent support carousel 45 with a plurality of reagent container supports 48 thereon, a homing and indexing device 58 for identifying a home position (original point signal) for the reagent support carousel and for identifying relative positions of reach reagent container support based on the subsequent movements of the drive means from the home position, a drive means 55 for rotating the carousel and positioning a preselected reagent container support in a reagent supply zone (column 5, line 67- column 6, line 5, Figs. 3, 5-8). However, Sakurada fails to recite a reagent

positioned over a reaction and a metallic object with a metal proximity detector. Additionally, Sakurada is silent regarding the use of an air mixer.

Rokugawa teaches an apparatus for delivering reagents to reaction containers wherein a plurality of reagent 68 are supported on a reagent carousel 64 which is positioned above a reaction carousel. A reagent delivery actuator means 100 for engaging a reagent container and initiating delivery of reagent (Fig. 1). Such a reagent delivery system would provide improved automatic chemical analysis with which it is possible to eliminate dead space in the reagent passage, reduce size, reduce distribution time and eliminate cross contamination (col. 1, lines 38-43).

Gibbs *et al* disclose a device which may be used in combination with devices to treat specimen material to prepare it for subsequent microscopic examination. The device of Gibbs *et al* disclose a specimen support tape 2 which is drawn through the device and a vortex mixer with outlets 14, or jet needles 22, for mixing a reagent and diluents with a specimen material before examination (column 3, lines 10-25, Figs. 2, 4). Air is supplied from the chamber and issues from an opposing outlet pair 14 between the biological mixture's edge and the edge of the tape, such that the pool is pushed back towards the middle of the tape (column 3, lines 1-7, Fig. 3). Such use of a air mixer would conveniently mix very small samples and reduce the possibility of cross-contamination (column 1, lines 21-39).

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided the apparatus of Sakurada *et al* with a reagent distributor positioned above the reaction carousel, as taught by Rokugawa, in order to provide improved automatic chemical analysis with which it is possible to eliminate dead space in the reagent

Application/Control Number: 10/137,169

Page 7

Art Unit: 1743

passage, reduce size, reduce distribution time and eliminate cross contamination. Additionally, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided the method of Sakurada et al with air mixer for stirring a sample and reagent via a gas stream, as taught by Gibbs *et al*, in order to conveniently mix very small samples and reduce the possibility of cross-contamination (column 1, lines 21-39).

With respect to the use of a slide it would have been obvious to one of ordinary skill in the art to have replaced the cuvette of Sakurada with a slide carousel, since microscope slides and cuvettes are known equivalents for biological analysis the analyzer art, see (Kamentsky et al, USP 5,107,422, col.4, lines 22-25).

With respect to the use of a metal proximity detector, it would have been obvious matter of design choice to replace the optical sensor of Sakurada with a metal proximity sensor, since applicant has not disclosed that a metal proximity sensor solves any stated problem or is for any particular purpose and it appears that the invention would perform equally well with an optical sensor.

Double Patenting

9. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

10. Claims 72-115 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-29 of U.S. Patent No. 5,595,707. Although the conflicting claims are not identical, they are not patentably distinct from each other because both claims recite an automated biological reaction apparatus comprising: a rotatable slide support carousel; a plurality of slide supports mounted on the slide support carousel in a circular array for supporting a plurality of slides; drive means engaging the slide support carousel for rotating the slide support carousel; a reagent delivery system for applying a predetermined quantity of reagent to one of the slides on one of the slide supports positioned, by rotation of the slide support carousel, in a reagent delivery zone; a vortex mixing assembly positioned at a vortex agitation zone, the vortex mixing assembly having a nozzle for directing fluid at a vortex agitation zone of one of the slides on one of the slide supports and being positioned at the vortex agitation zone. If the application claim is broader or more generic than the patent claim, the application claim is anticipated by the patent claims. *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993).

Allowable Subject Matter

11. Claims 83-90, 97-100, 107 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

The following is a statement of reasons for the indication of allowable subject matter: the prior art fails to teach or suggest the instant biological reaction apparatus which includes having a releasable reagent support carousel with a plurality of reagent container supports thereon, a homing and indexing device for identifying a home position for both the reagent support carousel

Application/Control Number: 10/137,169

Page 9

Art Unit: 1743

and slide support carousel and for identifying relative positions of each slide and reagent container support based on the subsequent movements of the drive means from the home position wherein the slide support includes a pivot support with a pivot axis such that the slide support plate is pivotally mounted on the pivot support for rotation around the pivot axis from a horizontal position to a slide draining position.

Conclusion

12. No claims allowed.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to P. Kathryn Bex whose telephone number is (703) 306-5697. The examiner can normally be reached on Mondays-Thursdays, alternate Fridays from 6:00 am to 3:30 pm EST. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 308-4037.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0661.

Kathryn Bex

P. Kathryn Bex
Patent Examiner
AU 1743
January 23, 2003

Jill Warden
Jill Warden
Supervisory Patent Examiner
Technology Center 1700

Notice of References Cited

Application/Control No.

10/137,169

Applicant(s)/Patent Owner

Reexamination
COPELAND ET AL

Examiner

P. Kathryn Bex

Art Unit

1743

Page 1 of 1

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
	A	US-5,107,422	04-1992	Kamentsky et al.	382/133
	B	US-			
	C	US-			
	D	US-			
	E	US-			
	F	US-			
	G	US-			
	H	US-			
	I	US-			
	J	US-			
	K	US-			
	L	US-			
	M	US-			

FOREIGN PATENT DOCUMENTS

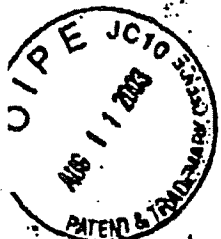
*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	Classification
	N					
	O					
	P					
	Q					
	R					
	S					
	T					

NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	
	V	
	W	
	X	

A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
 Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

EXHIBIT D



PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
(Case No. 97,008-Y)

In re Application of:

COPELAND, et. al

Serial No.: 10/137169 ✓

Filed: May 2, 2002

For: Automated Biological
Reaction Apparatus

Group Art Unit: 1743

Examiner: P. Bex

RECEIVED
AUG 15 2003
TC 1700

Commissioner for Patents
Box 1450
Alexandria, VA 22313-1450

REPLY TO FEBRUARY 5, 2003 OFFICIAL ACTION

This is a Reply to the February 5, 2003 Official Action for the above-captioned U.S. patent

application. Please amend the above-identified application as follows:

Amendments to the Claims are reflected in the listing of claims which begins on page 2 of this paper.

Remarks begin on page 11 of this paper.

An Appendix including a copy of a Terminal Disclaimer is attached following page 13 of this paper.


Listing Of Claims:

Claims 1-71 (cancelled)

72. (Currently amended) A biological reaction apparatus for dispensing a selected reagent to a slide containing a sample, said biological reaction apparatus comprising:

a reagent carousel having a plurality of reagent container supports thereon;

a homing and indexing device, operatively coupled to the reagent carousel, for identifying the position of each reagent container support with reference to a home position;

 a motor engaging the reagent carousel and operatively coupled to said homing and indexing device, for rotating the reagent carousel and positioning a preselected reagent container support in a reagent supply zone, wherein said reagent supply zone is oriented so that reagent in a container in said preselected reagent container support is dispensable to a slide and wherein each of the reagent container supports is arranged to accommodate a reagent container such that it is positioned above a slide when in the reagent supply zone whereby the reagent is dispensable from a lower end of said container onto a slide;

a sample carousel arranged beneath said reagent carousel for cooperation therewith, and having a plurality of slide supports with each slide support engaging a slide having a substantially planar support surface, said slide having a reagent agitation zone for adding and mixing reagents thereto located on the slide's upper surface; and

an air mixer comprising an air jet and an air supply means positioned adjacent to a said reagent agitation zone for mixing reagents when in the air agitation zone, said air mixer directing a jet of air at the reagent agitation zone thereby inducing mixing in the reagent agitation zone.

~~wherein said reagent supply zone is oriented so that reagent in a container in said preselected reagent container support is dispensable to a slide and wherein each of the reagent container supports is arranged to accommodate a reagent container such that it is positioned above a slide when in the reagent supply zone whereby the reagent is dispensable from a lower end of said container onto a slide.~~

73. (Previously presented) The biological reaction apparatus of claim 72, wherein said sample carousel may be arranged to allow said sample supports to be positioned in said reagent supply zone.

74. (Previously presented) The biological reaction apparatus of claim 72, wherein the reagent carousel is rotatably mounted on a reagent carousel support, and

wherein the homing and indexing device further comprises a proximity detector and an object detectable by the proximity detector when the proximity detector and said object are in close proximity, one of said object and said proximity detector being mounted on the reagent carousel, and the other of the object and said proximity detector being mounted on the reagent carousel support in a position adjacent the path of the other.

75. (Previously presented) The biological reaction apparatus of claim 74, wherein said object is metallic and mounted on the reagent carousel, and

wherein the proximity detector is a metal proximity detector mounted on the reagent carousel support.

76. (Previously presented) The biological reaction apparatus of claim 75, wherein the reagent carousel is rotatably mounted on a reagent carousel support, the reagent carousel has a bar code zone, and

wherein the homing and indexing device further comprises a bar code reader mounted on the reagent carousel support in a position to read a bar code on a reagent container positioned in the bar code zone, whereby a bar code identifying the contents of a reagent container in the respective reagent container support can be read with reference to said home position by the bar code reader, and the reagent container containing said identified reagent can be automatically positioned in the reagent supply zone.

77. (Previously presented) The biological reaction apparatus of claim 76, further comprises a reagent delivery actuator positioned for engaging a reagent container positioned in the reagent delivery zone and initiating delivery of a predetermined volume of reagent from the reagent container to said slide.

78. (Previously presented) The biological reaction apparatus of claim 77, wherein the motor comprises a stepper motor having a rotational mode for rotating the reagent carousel and a braking mode resisting rotation of the reagent carousel.

79. (Previously presented) The biological reaction apparatus of claim 78, wherein the reagent carousel comprises a reagent support tray removably supported by a reagent tray support, the reagent support tray has indexing support feet on an underside thereof, the reagent tray support has receptors for the indexing support feet in an upper surface thereof, whereby the reagent support tray can be removed from the reagent tray support for reloading or refrigerated storage and can be replaced on the reagent support tray in the same indexed position.

7 80. (Previously presented) The biological reaction apparatus of claim 79, wherein each sample support comprises a slide support plate having a distal end, a proximal end and a slide support surface, the distal end having raised terminal and lateral distal guide tabs with guide tab termini, the proximal end having first and second lateral guides with opposed surfaces for engaging the lateral edges of a slide, the distance between the slide support surface and the guide tab termini being less than a microscope slide thickness.

81. (Previously presented) The biological reaction apparatus of claim 80, wherein the slide support plate comprises a distal support section at the distal end and a proximal support section at the proximal end, the proximal support section comprising an inflexible support and a flexible arm with opposed lateral edges, and the distance between the slide engaging surfaces is less than a microscope slide width, whereby the slide engaging surfaces apply a positive pressure against the edges of a slide engaged therewith.

82. (Previously presented) The biological reaction apparatus of claim 81, wherein the distance between the slide engaging surfaces is from 20 to 24mm.

83. (Previously presented) The biological control apparatus of claim 82, further including a pivot support with a pivot axis, wherein the slide support plate is pivotally mounted on the pivot support for rotation around the pivot axis from a horizontal position to a slide draining position.

84. (Previously presented) The biological reaction apparatus of claim 83, wherein the pivot axis is defined by a pivot rod and a pivot rod receptor in sliding engagement therewith, one of the pivot rod and the pivot rod receptor being attached to or integral with the slide support and the other of the pivot rod and pivot rod receptor being attached to or integral with the pivot support.

85. (Previously presented) The biological reaction apparatus of claim 84, wherein the pivot axis is defined by two pivot rods and pivot rod receptors.

86. (Previously presented) The biological reaction apparatus of claim 82, wherein the slide support surface slopes downward from the proximal end to the distal end, the plane of the slide support surface forming an angle with the pivot axis of from 0.3 to 1 degree.

87. (Previously presented) The biological reaction apparatus of claim 83, wherein the slide support includes a lateral tilt cam surface for engagement by a tilt actuator.

88. (Previously presented) The biological reaction of claim 83, further comprising a rotational bias means for retaining the support surface in the substantially horizontal position when the tilt cam surface is not engaged by a tilt actuator.

89. (Previously presented) The biological reaction apparatus of claim 88 characterised in that the rotational bias means is a spring.

90. (Previously presented) The biological reaction apparatus of claim 83, wherein the pivot support has a pivot stop means positioned to abut a surface of the slide support for stopping pivotal rotation of the slide support when it has been pivoted to the slide draining position.

91. (Previously presented) The biological reaction apparatus of claim 73, wherein the homing and indexing device is operatively coupled to the slide support carousel, for identifying the position of each said slide support with reference to a home position; and

wherein the motor, engaging the slide support carousel and operatively coupled to said homing and indexing device, rotates the slide support carousel and positions a slide support in a reagent delivery zone.

92. (Previously presented) The biological reaction apparatus of claim 91, wherein the slide support carousel is rotatably mounted on a slide carousel support,

wherein the homing and indexing device comprises a proximity detector and an object detectable by the proximity detector when the proximity detector and said object are in close proximity, one of said object and said proximity detector being mounted on the slide support carousel, and the other of the object and said proximity detector being mounted on the slide carousel support in a position adjacent the path of the other.

93. (Previously presented) The biological reaction apparatus of claim 93, wherein said object is metallic and mounted on the slide support carousel and the proximity detector is a metal proximity detector mounted on the slide carousel support.

94. (Previously presented) The biological reaction apparatus of claim 91, wherein the slide support carousel is rotatably mounted on a slide carousel support,

wherein the slide support carousel has a bar code zone, and

wherein the homing and indexing device comprises a bar code zone, reader mounted on the slide carousel support in a position to read a bar code on a slide positioned in the bar code zone.

95. (Previously presented) The biological reaction apparatus of claim 91, characterised in that the motor comprises a stepper motor having a rotational mode for rotating the slide support carousel and a braking mode resisting rotation of the slide support carousel.

96. (Previously presented) The biological reaction apparatus of claim 95, further comprising a heating device for heating the samples.

97. (Currently amended) The biological reaction apparatus of claim 96, wherein the heating device comprises an air supply chamber communicating with the air distribution manifold,

start-up and operational heating means positioned in the path of air passing from the air supply chamber to ~~the~~an air distribution manifold, the start-up heating means comprising means for heating air until the heating chamber has reached an operational temperature, and the operational heating means comprising means for heating air until the heating chamber has reached said operational temperature and for intermittently heating air thereafter to maintain the heating chamber at an operational temperature.

98. (Previously presented) The biological reaction apparatus of claim 97, wherein the heating device includes a fan positioned to force air into the air distribution manifold through the air supply chamber, said fan including air temperature responsive means for increasing the rotational speed of said fan when the air temperature entering the air distribution manifold falls below a desired operational temperature.

99. (Previously presented) The biological reaction apparatus of claim 96, further comprising a temperature sensing device positioned in the path of heated air entering ~~the~~an air distribution manifold for detecting the temperature of said heated air.

100. (Previously presented) The biological reaction apparatus of claim 99, wherein the temperature sensing device is a thermistor encased in a heat sensitivity reducing jacket.

101. (Previously presented) The biological reaction apparatus of claim 72, further comprising a rinse station, a rinse solution applicator positioned adjacent the rinse station, the rinse solution applicator comprising at least one nozzle positioned for directing a stream of rinse liquid onto a rinse solution impact zone of a sample support.

102. (Currently amended) The biological reaction apparatus of claim 72, further comprising an evaporation inhibiting liquid application station, evaporation inhibiting liquid applicator positioned adjacent ~~the~~to an application station, the evaporation inhibiting liquid applicator comprising at least one nozzle positioned for directing a stream of evaporation inhibiting liquid onto a preselected evaporation inhibiting liquid impact zone of a sample support.

103. (Previously presented) An automated biological reaction apparatus of claim 102, wherein the evaporation inhibiting liquid application station is in the reagent delivery zone.

104. (Previously presented) The biological reaction apparatus of claim 72, wherein the air mixer includes a vortex agitation mixer having a nozzle for directing air at the air agitation zone, said sample support being positionable in the air agitation zone.

105. (Previously presented) The biological reaction apparatus of claim 104, wherein the vortex agitation mixer comprises a nozzle for applying at least one gas stream to an off-center area of the surface of liquid on a slide in the air agitation zone.

106. (Previously presented) The biological reaction apparatus of claim 105, wherein the vortex agitation mixer comprises a first nozzle adjacent to a distal end of a slide support in the air agitation zone for directing a first gas stream to a first off-center area of the surface of the liquid on a slide in the air agitation zone, and a second nozzle adjacent to a proximal end of a slide support in the air agitation zone for directing a second gas stream to a second off-center area of the surface of the liquid on a slide in the air agitation zone, the first and second gas streams being in opposite directions and the first and second off-center areas being on opposite sides of the center of the surface of a liquid on a slide in the air agitation zone.

107. (Previously added) The biological reaction apparatus of claim 72, further comprising apparatus for providing a sample rinse liquid within a selected temperature range, such apparatus comprising:

a container for receiving liquid;

temperature regulator, operatively mounted on said container, for maintaining liquid in the container within a selected temperature range; and

means, operatively coupled to said container, for delivering liquid at a temperature within said selected temperature range from the container to said sample.

108. (Previously presented) The biological reaction apparatus of claim 107, further comprising a safety thermostat connected to the heating device for terminating a flow of power to the heating device if the temperature of the container exceeds a predetermined safety limit.

109. (Previously presented) The biological reaction apparatus of claim 94, further comprising a bar code cleaner for cleaning bar codes on the slides.

110. (Previously presented) The biological reaction apparatus of claim 108, further comprising draining means for draining rinse solution from a sample.

111. (Previously presented) The biological reaction apparatus of claim 110, characterised in that the drain means comprises a jet drain for directing a jet of fluid across an upper surface of a slide.

112. (Currently amended) The biological reaction apparatus of claim 108, wherein the rinse solution applicator comprises a first rinsing means at a beginning of the a rinse zone and a second rinsing means at an end of the rinse zone.

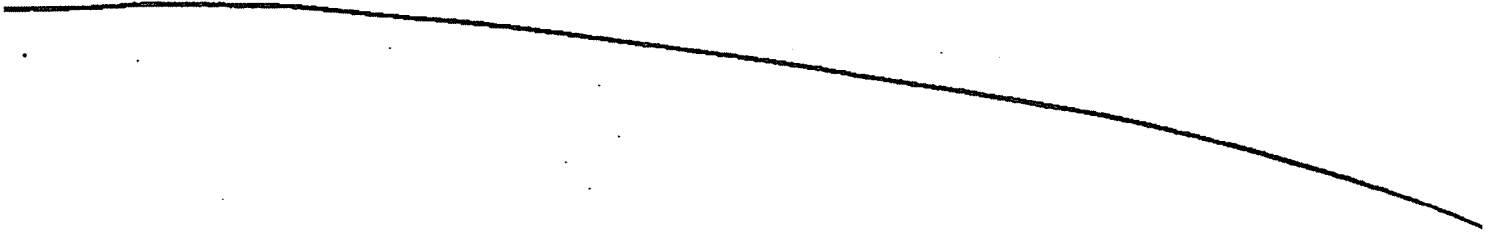
113. (Previously presented) The biological reaction apparatus of claim 112, wherein the first rinsing means includes at least one nozzle for depositing a layer of rinse liquid onto an upper surface of a slide positioned at the beginning of the rinse zone and the second rinsing means includes sweeping means for sweeping the layer of rinse liquid off of the slide when the slide reaches the end of the rinse zone.

114. (Previously presented) The biological reaction apparatus of claim 113, wherein the first rinsing means and the second rinsing means are spaced from one another so that a predetermined period of time transpires during the transport of the slide between the first and second rinsing means before the layer of rinse liquid is swept off of the slide.

115. (Previously presented) The biological reaction apparatus of claim 114, wherein the sweeping means of the second rinsing means comprises fluid pulsing means for forming pulsed

streams of rinse liquid, alternately directed at one and then an other of longitudinal edges of the slides, to sweep the layer of rinse liquid off of the slide.

31



REMARKS

Claims 72-115 are pending in the application. Claims 72, 97, 99, 102 and 112 have been amended to overcome the Examiner's section 112 rejection, and the dependency of claim 98 has been altered in view of the cancellation of claim 97 from the application. No new matter has been added to the application by way of these amendments.

The Examiner's specification and claim objections and rejections are overcome or are traversed as set forth below.

I. THE 112, 2nd PARAGRAPH REJECTION

The Examiner rejected claims 72-115 under 35 U.S.C. § 112, second paragraph as being incomplete for omitting essential elements. The Examiner also specifically rejected claims 97, 102 and 112 for various deficiencies.

The Examiner's rejection of claims 72-115 for omitting elements has been overcome by amending claim 72 to recite the essential elements identified by the Examiner. This claim 72 amendment overcomes the Examiner's rejection of claims 72-115 on this ground.

The Examiner's rejections of claims 97 and 99 are overcome by amending claims 97 and 99 to replace the term "the air distribution manifold" with the term "an air distribution manifold".

The Examiner's rejection of claim 102 has been overcome by amending the term "the application station" to read "an application station".

The Examiner's rejection of claim 112 has been overcome by amending the term "the rinse zone" to read "a rinse zone".

II. TRAVERSE OF THE OBVIOUSNESS REJECTIONS

A. Traverse Of The Hulette and Kelln Obviousness Rejection

The Examiner rejected claims 72-82, 91-96 and 101-106 for being obvious of Hulette (WO 85/03571) in view of Kelln et al. (USP 4,764,342). It is the Examiner's position that Hulette in combination with Kellen et al. renders obvious the claims recited above.

Claims 72-82, 91-96 and 101-106 are not obvious over Hulette in view of Kelln et al. at least because the references do not disclose or suggest (1) a reagent carousel having a plurality of reagent

container support and oriented so that reagent in a container in said preselected reagent container support is dispensable to a slide . . . ; and (2) an air mixer capable of mixing reagents on a slide.

It is the Examiner's position that Hulette discloses the claimed reagent carousel. However, Hulette does not disclose a reagent carousel. Instead, Hulette discloses a carousel that dispenses solid tablets into cuvettes. Moreover, the liquid reagents that are dispensed in Hulette are not dispensed from carousels. Instead, "liquid" reagents are dispensed by "diluent/liquid reagent dispenser 50." (See Hulette p. 22, lines 1-3). Figure 3 demonstrates that "diluent/liquid reagent dispenser 50" is not a carousel. Thus, claims 72-115 are not obvious because Hulette does not disclose a liquid reagent carousel.

Secondly Hulette or Kelln et al. are both directed to analysis systems that use cuvettes. In contrast, the claimed invention is directed to analysis systems that use slides. Using air to mix reagents on slides is quite different from mixing reagents held cuvettes. For example, it is critical that reagents located on a slide are not forced off the slide during mixing. This is not a concern with cuvettes since the reagents are located in a container. Thus, claims 72-115 are not obvious over Hulette in combination with Kelln et al. because neither reference discloses using air to mix reagents located on a slide.

B. Traverse Of The Sakurada, Rokugawa and Gibbs et al. Obviousness Rejection

The Examiner also rejected claims 72-79 and 102-106 for being obvious over Sakurada (USP 4,346,056) in view of Rokugawa (USP 4,844,868) and Gibbs et al. (USP 3,854,703).

Claims 72-79, and 102-106 are not obvious over the prior art. The prior art fails at least to disclose a reaction apparatus with a "homing and indexing device, operatively coupled to the reagent carousel, for identifying the position of each reagent container support with reference to a home position".

Sakurada discloses an analyzer including a detector 58. Detector 58 includes three photocouplers oriented in a vertical position. (See Sakurada col. 5, lines 66-68). The photocouplers identify "discrimination holes 53" on each reagent vessel holder 45. (Id. col. 6, lines 8-15). Only one reagent vessel includes a discrimination hole that is detectable by the lowest photocoupler. (Id. at col. 5 line 67 to col. 6, line 2). This is the "original point signal" or home position. Detecting the original point signal causes "[the device] to move the desired reagent vessel 48 arranged the given order to a given injection point" (Id. at col. 6, lines 2-5). Moreover, the remaining discrimination holes discriminate up to three different types of reagent containers – one from the other. In Sakurada, therefore, the "home position" would be the location of the photocouplers.

Based on this teaching, it is clear that the Sakurada reference does not disclose a device that can “identify the position of each reagent container support with reference to the home position.” Instead the Sakurada device can only identify the positions of the reagent containers when the device is in the home position – when the container with the “original point signal” is adjacent to the photodetectors. In all other positions, the Sakurada device does not know where the containers are relative to the home position.

In the claimed invention, the device always knows the position of each container relative to the home location. In this way, the device does not have to return to the home position, as in the prior art, before a reagent can be supplied to a new test sample. For at least this reason, claims 72-79 and 102-106 are believed to be patentable over the prior art of record.

III. THE DOUBLE PATENTING REJECTION

The Examiner rejected claims 72-115 under the judicially created doctrine of obviousness type double patenting as being unpatentable for claims 1-29 of U.S. Patent No. 5,595,707.

This rejection has been overcome by filing a Terminal Disclaimer vis-à-vis U.S. Patent Number 5,595,707 contemporaneously with the filing of this Reply.

IV. ALLOWABLE SUBJECT MATTER

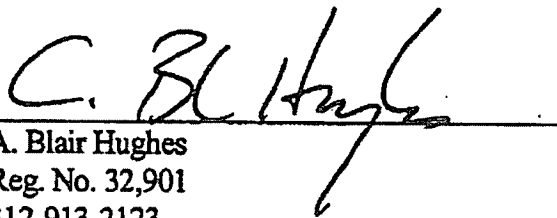
The Applicants thank the Examiner for indicating that claims 83-90, 97-100 and 107 would be allowable if rewritten to overcome the rejections under 35 USC 112, second paragraph. We respectfully point out that claims 108 and 110-115 depend either directly or indirectly upon allowable claim 107. Therefore, the applicants believe that the Examiner should have indicated that claims 107-108 and 110-115 would also be allowable if rewritten to overcome the Examiner's rejection under 35 USC 112, second paragraph.

Conclusion

Pending application claims 72-115 are believed to be patentable for the reasons indicated above. Favorable reconsideration and allowance of all pending application claims is, therefore, courteously solicited.

Respectfully submitted,

McDonnell Boehnen Hulbert & Berghoff

By: 
A. Blair Hughes
Reg. No. 32,901
312-913-2123

DATED: August 5, 2003

(Case No. 97,008-Y)

In Application of:

COPELAND, et. al

Serial No.: 10/137169

Filed: May 2, 2002

For: Automated Biological
Reaction Apparatus

Group Art Unit: 1743

Examiner: P. Bex

RECEIVED

AUG 15 2003

TC 1700

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

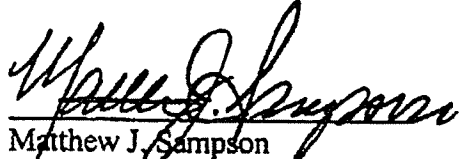
Sir:

TRANSMITTAL LETTER

In regard to the above identified application:

1. We are transmitting herewith the attached:
 - a. Petition for Three Month Extension of Time
 - b. Reply to February 5, 2003 Official Action
 - c. Terminal Disclaimer
 - d. Return Receipt Postcard
2. With respect to additional fees:
 - a. Attached is a check in the amount of \$930.00 (Extension of Time Filing Fee)
 - b. Attached is a check in the amount of \$110.00 (Terminal Disclaimer Filing Fee)
3. Please charge any additional fees or credit overpayment to Deposit Account No.13-2490. A duplicate copy of this sheet is enclosed.
4. CERTIFICATE OF MAILING UNDER 37 CFR § 1.8: The undersigned hereby certifies that this Transmittal Letter and the paper, as described in paragraph 1 hereinabove, are being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Arlington, Virginia 22313-1450 on this 5th¹ day of August, 2003.

By:


 Matthew J. Sampson
 Reg. No. 35,999

 McDONNELL BOEHNEN,
 HULBERT & BERGHOFF
 300 SOUTH WACKER DRIVE
 CHICAGO, ILLINOIS 60606
 TELEPHONE (312) 913-0001